#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Tchao, R. Examiner: Wong, L. (Anticipated)

Serial No.: 09/472,490 Group Art Unit: 1302 (Anticipated)

Filed: December 23, 1999 Docket: 102-302 RES/CON

For: Chemotaxis Assay Dated: June 11, 2008

Commissioner for Patents

P.O. Box 1450 Alexandria, VA 22313-1450

# PETITION TO WITHDRAW HOLDING OF ABANDONMENT BASED ON FAILURE TO RECEIVE OFFICE ACTION UNDER 37 CFR 1.181(a)

Sirs:

The PTO has issued a "Notice of Abandonment" on May 12, 2008 in the aboveidentified application. Such Notice was issued in error, as discussed below. Accordingly, Applicants request a withdrawal of the holding of abandonment.

The Notice of Abandonment (Exhibit A) states that the application was abandoned in view of: "[t]he decision by the board of Patent Appeals and Interference rendered on 28

January 2008 and because the period for seeking court review of the decision has expired and there are no allowed claims".

The decision by the board of Patent Appeals and Interference dated January 28, 2008 (Exhibit B) ordered that the decision of the Examiner rejecting claims 46-48, 50 based on 35 USC §112, first paragraph, and based on 35 USC §251 rejection be REVERSED.

Docket No: 102-302 RES/CON

Serial No.: 09/472,490 Applicants: Tchao, R. Filed: December 23, 1999

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Additionally, the Board ordered that the decision by the Examiner rejecting claims 46-50 based on a judicially created doctrine of obviousness patenting, and based on a defective reissue oath/declaration be AFFIRMED. Furthermore, the Board "ordered that the case be returned to the Examiner for action consistent herewith."

However, the Examiner failed to issue and action consistent with the Board's decision. In fact, the Examiner only issued a Notice of Abandonment. Thus, the Applicant petitions to withdraw holding of Abandonment based on the failure to receive an office action consistent with the Board of Patent Appeals decision.

Furthermore, to advance prosecution, enclosed herewith is a terminal disclaimer

(Exhibit C) in response to the rejection under the judicially created doctrine of obviousness

patenting over claims 1-19 of RE38,383 E. Additionally, enclosed herewith is a

Supplemental Reissue Declaration (Exhibit D) to overcome the rejecting based on a

defective reissue oath/declaration. Thus, in view of the decision by the Board of Patent

Appeals and the enclosed submissions, the application is believed to be in condition for

allowance.

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Applicants: Tchao, R. Filed: December 23, 1999

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Applicants believe no fee is required to file this Petition (MPEP 711.03(e)). If there are any questions regarding this response, the Applicants' undersigned attorney at the telephone number provided below should be contacted as soon as possible.

Respectfully submitted,

Anna Hea L. Gallo, Esq. Registration No.: 50,279 Attorney for Applicant(s)

HOFFMANN & BARON, LLP 6900 Jericho Tumpike Syosset, New York 11791 (973) 331-1700

Encl.: Notice of Abandonment (Exhibit A)
Decision on Appeal (Exhibit B)
Terminal Disclaimer (Exhibit C)
Supplemental Reissue Declaration (Exhibit D)



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria Virginia 22513-1450 www.usphg.gov

PPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR			ATTORNEY DOCKET NO	CONFIRMATION NO
09/472,490	12/23/1999		RUY TCHAO			102-302RE/CO	8828
HOFFMANN & BARON, LLP 6900 JERICHO TURNPIKE		12/2008			7	EXAM	INER
						WONG, I	ESLIE A
SYOSSET, NY	11791	1			18	ART UNIT	PAPER NUMBER
		1 19	MAY 1	4 2008	177	1794	
		in the				MAIL DATE	DELIVÉRY MODE
					- 1	05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



EXHIBIT A

N 6 - 64 - 1 - 1	09/472.490	TCHAO, RUY	TCHAO, RUY	
Notice of Abandonment	Examiner	Art Unit		
	Leslie Wong	1794		
The MAILING DATE of this communi	ication appears on the cover sheet v	vith the correspondence address	••	
This application is abandoned in view of				
Applicant's failure to timely file a proper reply     (a) A reply was received on (with a Cer_ period for reply (including a total extension)	rtificate of Mailing or Transmission date of time of month(s)) which exp	ired on		
(b) A proposed reply was received on				
(A proper reply under 37 CFR 1.113 to a fit application in condition for allowance; (2) a Continued Examination (RCE) in compliant	timely filed Notice of Appeal (with app			
(c) A reply was received on but it does final rejection. See 37 CFR 1 85(a) and 1.			ne non-	
(d) No reply has been received.				
Applicant's failure to timely pay the required is from the mailing date of the Notice of Allowand		le, within the statutory period of thre	e months	
(a) The issue fee and publication fee, if appl	icable, was received on (with a statutory period for payment of the issu			
(b) The submitted fee of \$ is insufficient.	A balance of \$ is due.			
The issue fee required by 37 CFR 1.18 is	\$ The publication fee, if requir	ed by 37 CFR 1.18(d), is \$		
(c) The issue fee and publication fee, if applica	ble, has not been received.			
Applicant's failure to timely file corrected drawin Allowability (PTO-37).	ngs as required by, and within the three	e-month period set in, the Notice of		
<ul> <li>(a) Proposed corrected drawings were received after the expiration of the period for reply.</li> </ul>	d on (with a Certificate of Mailin	g or Transmission dated), wh	nich is	
(b) No corrected drawings have been received				
The letter of express abandonment which is sig the applicants.	gned by the attorney or agent of record	, the assignee of the entire interest,	, or all of	
<ol> <li>The letter of express abandonment which is sign. 1.34(a)) upon the filing of a continuing application.</li> </ol>		a representative capacity under 37	CFR	
<ol> <li>The decision by the Board of Patent Appeals a court review of the decision has expired and the</li> </ol>		v 2008 and because the period for	seeking	
7. The reason(s) below:				
	/Leslie Wong/ Primary Examiner,	Art Unit 1794		
Petitions to revive under 37 CFR 1.137(a) or (b), or request minimize any negative effects on patent term S. Patent and Trademark Office	s to withdraw the holding of abandonment	under 37 CFR 1,181, should be promptly	y filed to	
S. Patent and Trademark Office TOL -1432 / Rev. 04-011	Notice of Abandonment	Part of Paper No. 3	20080500	

Application No.

Applicant(s)





UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addems COMMISSIONER FOR PATIENTS FO Box 1430 Alexandra, Virgina 22313-1450 are upto go.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/472,490	12/23/1999	RUY TCHAO	102-302RE/CO	8828
23869 HOFFMANN	7590 01/28/2008 & BARON, LLP		EXAM	INER
6900 JERICHO	) TURNPIKE		WONG, LESLIE A	
SYOSSET, NY 11791		.1791	ART UNIT	PAPER NUMBER
			1794	
			MAIL DATE	DELIVERY MODE
			01/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



EXHIBIT B

#### UNITED STATES PATENT AND TRADEMARK OFFICE

# BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte RUY TCHAO

Appeal 2007-4229 Application 09/472,490<sup>t</sup> Patent 5,601,997 Technology Center 1700

Decided: January 28, 2008

Before TEDDY S. GRON, ADRIENE LEPIANE HANLON, and CAROL A. SPIEGEL. Administrative Patent Judges.

SPIEGEL, Administrative Patent Judge.

DECISION ON APPEAL

#### INTRODUCTION

Application 09/472,490, filed 23 December 1999, is said to be a continuation of Application 09/159,427, filed 23 September 1998, as a reissue of Patent 5,601,997 ("the '997 patent"), which issued 11 February 1997, based on Application 08/383,058, filed 3 February 1995. The real party-in-interest is said to be Ruy Tchao (APPEAL BRIEF PURSUANT TO 37 C.F.R. §41.37 IN RESPONSE TO NOTICE OF NON-COMPLIANT BRIEF, filed 8 December 2006 ("App. Br.") at 3).

Ruy Tchao ("Appellant") appeals under 35 U.S.C. § 134 from the Examiner's final rejection of claims 46-50, all of the pending claims. Claim 49 is also objected to as being dependent upon a rejected base claim (Ans.<sup>2</sup> 5). We have jurisdiction under 35 U.S.C. § 6(b). We AFFIRM.

#### SUBJECT MATTER ON APPEAL

The claims on appeal are directed to a cell migration assay comprising measuring the movement of cells across a radiation opaque membrane, wherein the assay does not destroy the cells being measured. Claim 46, the sole independent claim, is illustrative and reads (App. Br. 18):

A cell migration assay procedure comprising measuring the migration of cells across a radiation opaque membrane wherein said procedure is non-destructive of said cells.

#### THE REJECTIONS

Claims 46-50 stand rejected for obviousness-type double patenting of claims 1-19 of US Patent RE38,863 E.<sup>3</sup> "This rejection is not being appealed as, if the claims are otherwise found to be allowable, an appropriate terminal disclaimer will be filed" by Appellant (App. Br. 4; see also App. Br. 16). Therefore, we AFFIRM the rejection of claims 46-50 for obviousness-type double patenting of claims 1-19 of RE38,863 E since a proper terminal disclaimer has not yet been filed by Appellant.

<sup>&</sup>lt;sup>2</sup> Examiner's Answer mailed 23 February 2007 ("Ans.").

<sup>&</sup>lt;sup>3</sup> According to the Examiner, claims 46-50 stand "provisionally rejected under the judicially created doctrine of obviousness-type double patenting ... over claims 1-15 and 38-41 of copending Application No. 09/966,831" (Ans. 4). Application No. 09/966,831 issued as reissue patent US RE38,863 E on 1 November 2005. Thus, this is no longer a provisional rejection.

Claims 46-50 stand rejected under 35 U.S.C. § 251 as based on a defective declaration (Ans. 4). "This rejection is also not being appealed as, if the claims are found to be otherwise allowable, an appropriate supplemental oath/declaration pursuant to 37 C.F.R. § 1.75(b)(1) will be filed" by Appellant (App. Br. 4; see also App. Br. 16). Therefore, we AFFIRM the rejection of claims 46-50 under § 251 as based on a defective reissue oath/declaration since a proper oath/declaration has not yet been filed by Appellant.

Claims 46-48 and 50 stand rejected under 35 U.S.C. § 112, first paragraph, as not enabled throughout their full scope (Ans. 5); and, under 35 U.S.C. § 251 as improperly broadening the scope of the claims of the '997 patent (Ans. 6). We discuss these last two rejections below.

## FINDINGS OF FACT

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

- [1] Originally issued claim 15 of the '997 patent reads, "A <u>chemotaxis</u> <u>assay procedure</u> comprising measuring the migration of cells across a radiation opaque membrane, wherein said procedure is non-destructive of said cells" (emphasis added).
- [2] Claim 46 of the reissue application on appeal differs from originally issued claim 15 of the '997 patent only in its preamble, which recites "A cell migration assay procedure."
- [3] According to the '997 patent, 4 such radiation opaque membranes permit the measurement of radiation emitted from labeled cells that have migrated

<sup>4</sup> We cite the '997 patent in lieu of the reissue application on appeal.

Application 09/472,490 Patent 5,601,997

through the radiation opaque membrane without interference from radiation emitted from the labeled cells that have not migrated, without the need to remove the non-migrated cells from the radiation opaque membrane. This is a significant advantage of the present invention over the prior art procedures, not only because it avoids the tedious steps of removing the filter, and scraping the non-migrated cells from the filter, but also because it is non-destructive of the cell sample and thus permits repeated measurements of the same test sample at different time intervals. ['997 patent 5:62 through 6:9.]

- In one embodiment, the '997 patent describes using a radiation opaque porous membrane to separate a well into two chambers, placing labeled cells into one chamber and a chemical agent into the other. Chemotaxis is said to cause labeled cells to migrate through the membrane into the other chamber in response to the chemical agent, wherein the amount of label on that side of the membrane, and thus the amount of migrated cells, can be measured at predetermined intervals ('997 patent 3:42 through 4:38).
- [5] The '997 patent defines chemotaxis as "the orientation or movement of an organism or cell in relation to a chemical agent" ('997 patent 1:14-15).
- [6] Both Appellant and the Examiner acknowledge that chemotaxis is but one method known for use in effecting cell migration (App. Br. 9; Ans. 5-6).

- [7] According to the Examiner, the disclosure of the '997 patent is limited to non-destructive <u>chemotaxis</u> assays because it does not disclose cell migration in response to any other stimulus (Ans. 5-6).
- [8] Further according to the Examiner, it would require "extensive experimentation" to use other methods of inducing cell migration, such as phototaxis, electrotaxis, or geotaxis, in response to an agent other than a chemical agent (Ans. 6).5
- [9] The Examiner concludes that the reissue claims have improperly broadened the scope of the originally issued claims because "Appellant does not teach any and all types of non-destructive assays or any and all types of inducing agents" (Ans. 6).
- [10] Appellant argues that the operative assay measurement is cell migration and chemotaxis is only one technique known to induce cell migration (App. Br. 9-10).
- [11] In other words, Appellant argues that use of a radiation opaque membrane as recited in claim 46 is independent of the particular stimulant causing the cells to migrate therethrough (App. Br. 10).
- [12] According to Appellant, so long as the membrane used in the assays has the properties described in the specification, no undue experimentation would have been necessary to practice the claimed steps in any cell migration assay (App. Br. 13).
- [13] Thus, Appellant submits that the originally filed application describes and enables a non-destructive cell migration assay

Taxis is the response of a cell or an organism to a directional (attractive or repulsive) stimulus. For example, the stimuli for chemotaxis, geotaxis, electrotaxis and phototaxis are a chemical, gravity, electric current and light, respectively.

procedure as recited in the appealed claims and that the requirements of § 251 have been satisfied (App. Br. 15).

#### DISCUSSION

#### A. Enablement

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application. ...". In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). "That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive." Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1212 (Fed. Cir. 1991). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). A number of factors are relevant to whether undue experimentation would have been required to practice the claimed invention, including "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art. (7) the predictability or unpredictability of the art. and (8) the breadth of the claims," Id., 858 F.2d at 737.

According to the Examiner, "extensive experimentation" would have been required to enable the full scope of the claims 46-48 and 50

because the '997 patent specification only discloses cell migration in response to a chemical stimulus (FFs 7-8). The Examiner did not characterize the extent of experimentation as undue. The Examiner did not provide a sufficient factual basis for concluding that undue experimentation would have been required, e.g., that a person of ordinary skill in the art, using the knowledge available to such a person and the disclosure of the '997 patent specification, could not have made and used the claimed invention. "Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching [of how to make and use the full scope of the claimed invention] is provided through broad terminology or illustrative examples." *In re Wright*, 999 F.2d at 1561 (Fed. Cir. 1993).

Therefore, we REVERSE the Examiner's rejection of claims 46-48 and 50 under § 112, first paragraph, for lack of enablement.

### B. Broadening reissue claims

"Section 251 allows patentees to correct 'errors' made during prosecution, such as claiming less than the patentee had a right to claim." *In re Clement*, 131 F.3d 1464, 1468 (Fed. Cir. 1997). In essence, the position of the Examiner is that Appellant has no right to the subject matter of reissue claims 46-48 and 50 because the '997 patent specification would not have enabled the full scope of these claims. Since the Examiner has failed to establish that the disclosure of the '997 patent specification would not have enabled the full scope of reissue claims 46-48 and 50, we also REVERSE the Examiner's rejection of claims 46-48 and 50 under § 251.

#### ORDER

Upon consideration of the record and for the reasons given, it is
ORDERED that the decision of the Examiner rejecting claims 4650 under the judicially created doctrine of obviousness patenting over
claims 1-19 of RE38,383 E is AFFIRMED:

FURTHER ORDERED that the decision of the Examiner rejecting claims 46-50 under 35 U.S.C. § 251 as based on a defective reissue oath/declaration is AFFIRMED;

FURTHER ORDERED that the decision of the Examiner rejecting claims 46-48 and 50 under 35 U.S.C. § 112, first paragraph, for lack of enablement is REVERSED;

FURTHER ORDERED that the decision of the Examiner rejecting claims 46-48 and 50 under 35 U.S.C. § 251 as improperly broadening the scope of the claims of Patent 5,601,997 is REVERSED; and,

FURTHER ORDERED that the case be returned to the Examiner for action consistent herewith.

# **AFFIRMED**

MAT

HOFFMAN & BARON, LLP 6900 Jericho Turnpike Syosset, New York 11791 Application 09/472,490 Patent 5,601,997

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application for Reissue of U.S. Patent No. 5,601,997

Applicant(s): Tchao, R. Examiner: Wong, L. (Anticipated)

Serial No.: 09/472,490 Group Art Unit: 1302 (Anticipated)

Filed: December 23, 1999 Docket: 102-302 RES/CON

For: Chemotaxis Assay Dated:

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

# TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT(S)

The owner, <u>Ruy Tchao</u>, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term **prior patent** No(s). <u>RE 38,863</u> as the term of said prior patent is defined in 35 U.S.C. 154 and 173, and as the term of said prior patent is presently shortened by any terminal disclaimer. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee. Its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of the prior patent, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;

is held unenforceable:

is found invalid by a court of competent jurisdiction;

is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;

has all claims canceled by a reexamination certificate;

is reissued; or

Application No.: 09/472,490 Docket No.: 102-302 CON/RES Terminal Disclaimer

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is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

 For submissions on behalf of a business/organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the business/organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. The undersigned is an attorney or agent of record. Reg. No. 50,279

Signature Date

Anna-lisa L. Gallo

Typed or printed name

(973) 331-1700

Telephone Number

- Terminal disclaimer fee under 37 CFR 1.20(d) included.
- PTO suggested wording for terminal disclaimer was unchanged.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

\* Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this certification. See MPEP § 324.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#### In Re Application for Reissue of U.S. Patent No. 5,601,997

Applicant(s): Tchao, R. Examiner: Wong, L. (Anticipated)

Serial No.: 09/472,490 Group Art Unit: 1302 (Anticipated)

Filed: December 23, 1999 Docket: 102-302 RES/CON

For: Chemotaxis Assay Dated:

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

#### SUPPLEMENTAL REISSUE DECLARATION

Sir:

I, Ruy Tchao, declare that I am a citizen of the United States and a resident of Flourtown, Pennsylvania, and:

that I believe that I am the original and first sole inventor of the subject matter claimed in

U.S. Patent No. 5,601,997 (hereinafter the '997 patent), entitled "Chemotaxis Assay Procedure";

that 1 have reviewed and understand the specification of the accompanying reissue application, including the claims;

that I believe that I am the original and first sole inventor of the subject matter which is claimed and for which a reissue patent is sought; and

that I acknowledge my duty to disclose to the U.S. Patent Office all information known to me to be material to patentability as defined in 37 C.F.R. §1.56. Every error in the '997 patent which was corrected in the present reissue application which was and is not covered by a prior oath/declaration submitted in this application arose without any deceptive intent on the part of the applicant.

I declare that all statements made herein of my own knowledge are true, and that all statements made upon information and belief are believed to be true, and further that these statements were made after being warned that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. §1001, and that such false statements may jeopardize the validity of this application or any patent issuing thereon.

Full name of sole or i	irst inventor Ruy T	chao, Ph.I	<u>).</u>			
Inventor's Signature	Runger	مسه	_ Date _	Jone	6,2008	
Residence 404 Cedar	Lane, Flourtown, F	PA 19031	Citizensh	ip U.S.A.		
Post Office Address	Flourism	PA 19	31			